4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-1212]

Wound Healing Scientific Workshop; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the following public workshop entitled "Wound Healing Scientific Workshop." The purpose of the workshop is to discuss nonhealing chronic wounds.

DATES: The public workshop will be held on April 28, 2022 (Day 1), 9 a.m. to 4 p.m. Eastern Time and April 29, 2022 (Day 2), 9 a.m. to 4 p.m. Eastern Time. Submit either electronic or written comments on this public workshop by June 28, 2022. See the SUPPLEMENTARY INFORMATION section for registration date and information.

ADDRESSES: The public workshop will be held in a virtual format.

You may submit comments as follows. See section III below for guidance on structuring comments. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before June 28, 2022. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 28, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to

https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2021-N-1212 for "Wound Healing Scientific Workshop." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper

submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: K. Dev Verma, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5327, Silver Spring, MD 20993, 240-402-0282, Kapil.Verma@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In 2020, through a Science Strategies program launched by the Office of New Drugs (OND) in the Center for Drug Evaluation and Research, the Division of Dermatology and

Dentistry collaborated with experts from the Center for Biologics Evaluation and Research, Center for Devices and Radiological Health, and OND's Division of Clinical Outcome Assessments to assess areas of unmet medical need and activity in the product development pipeline for wound healing. Because of high unmet medical need with relatively limited research and funding, FDA identified nonhealing chronic wounds as an area warranting prioritization. Root cause analyses indicated that barriers to product development for nonhealing chronic wounds involve, but are not limited to, deficient biological understanding, challenges in drug delivery, challenges in clinical trial execution, and limited commercial viability. Specific issues include the lack of current optimal preclinical animal models that are capable of properly recapitulating human wounds, heterogeneous natural history of different wounds, lack of alternative endpoints to complete wound closure, limited standardization between clinical trials, high rate of clinical trial failures, difficulties with participant enrollment in clinical trials, and a complex reimbursement environment.

FDA recognized the need for a multistakeholder Wound Healing Scientific Workshop to enhance awareness of these unmet medical needs and barriers, to seek external input, to support data sharing, and to communicate current regulatory thinking.

II. Topics for Discussion at the Public Workshop

During the 2-day workshop, FDA and wound-healing experts aim to outline the landscape of and review current standards for product development in the field of nonhealing chronic wounds, as well as identify challenges of implementing and conducting clinical trials, discuss potential solutions to overcome these challenges, and explore how current research in wound healing can be applied to promote innovative product development.

By building on the science of known physiological processes and principles of normal wound healing and recognizing factors that disrupt these mechanisms, the workshop anticipates that a better understanding of the complexity of chronic wounds will help illustrate the gaps in current treatment options.

Furthermore, hearing from patients and patient representatives regarding their understanding of the etiology and pathology of their nonhealing chronic wounds, as well as learning what is clinically meaningful to them and what their experiences have been with clinical trials, will further inform how wound healing measures might be improved upon to execute successful clinical trials and drive innovation.

III. Request for Specific Public Comments

FDA is also soliciting public comment on experiences with nonhealing chronic wounds. When submitting a comment, FDA requests that commenters identify whether they are a patient, caregiver, medical provider, product developer, or other stakeholder. FDA also requests that commenters answer the following questions based on their identifications:

1. If you are a patient or a caregiver of an individual who has experience living with a nonhealing chronic wound:
   a. Meaningful outcomes: What results of treatment would you consider meaningful to you (e.g., complete healing of the wound, partial healing of the wound, decreased pain, easier wound care/dressing changes)?
   b. Clinical trial experience: If you have been involved in a clinical trial to treat a nonhealing chronic wound, please describe your experience. If you have not been able to participate (e.g., not eligible), or if you have chosen not to participate in a clinical trial, please tell us why.
   c. Impact on quality of life: What aspects of the nonhealing wound(s) have the most significant impact on your quality of life (e.g., odor, pain, discharge, decreased mobility, burdensome wound care, etc.)? Please provide a specific example, if possible.
2. If you are a caregiver or loved one, in addition to the above questions:
   a. Challenges: Which aspect(s) of providing care have been the most challenging (e.g., logistics of coordinating appointments, burdensome wound care, affordability of products/supplies, access to treatment, emotional stress)?

b. Education/Training: Were you trained on how to care for your loved one and the individual's nonhealing chronic wound? If so, did the training and education that you were provided allow you to feel confident in your ability to perform dressing changes and other necessary care? Please explain.

3. If you are a healthcare provider:

   a. Wound types: What subtypes of nonhealing chronic wounds do you treat in your practice (e.g., diabetic foot ulcers, pressure wounds, arterial wounds, venous wounds)?

   b. Challenges: What have been your challenges to providing care to patients with nonhealing chronic wounds?

   c. Standard of Care: Do you utilize a standard of care protocol for your nonhealing chronic wound patients? If so, describe what standard of care protocol you utilize (specified by wound etiology).

   d. Products: What new products (e.g., drugs, devices, biologics, combination products) would you find helpful in treating nonhealing chronic wounds?

   e. Reimbursement: How does reimbursement affect your ability to provide care?

4. If you are a product developer/researcher:

   a. Challenges: What are strategic, operational, and tactical challenges (and possible solutions) to implementation of successful clinical trials for chronic, nonhealing wounds?

   b. Innovation: What are barriers (and possible solutions) to wound care research in the development of innovative wound care products?

5. If you are involved in the reimbursement landscape (e.g., Centers for Medicare and Medicaid Services, insurance payors, billers):

   a. Acceptable evidence: What is the current acceptable evidence for coverage decisions related to wound care products (devices, drugs, biologics, combination products)?

b. Challenges: What are challenges (and possible solutions) encountered in reimbursement-related decisions for wound care treatment?

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit the following website: https://woundhealingfda2022.eventbrite.com/. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register by April 3, 2022, by 11:59 p.m. Eastern Time. Registrants will receive confirmation when they have been accepted. Early registration is recommended because space is limited; therefore, FDA may limit the number of participants from each organization.

Streaming Webcast of the public workshop: This public workshop will be webcast at https://fda.zoomgov.com/j/1610233374?pwd=VTU5VDZid3FnaWJKMndOWXRMbmFSUT09. The link above should allow you to enter the webinar directly. If Zoom asks for a passcode, please use the case-sensitive passcode below.

Case-Sensitive Passcode for Zoom Webinar: eEG.p5

FDA has verified the website addresses in this document, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at https://www.regulations.gov. It may be viewed at the Dockets Management Staff (see ADDRESSES). A link to the transcript will also be available on the internet at https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/office-immunology-and-inflammation-division-dermatology-and-dentistry-ddd.

Dated: December 15, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021-27459 Filed: 12/17/2021 8:45 am; Publication Date: 12/20/2021]